§493.1251 Condition: Urinalysis.

Except for those tests categorized as waived, to meet the quality control requirements for urinalysis, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221.

[58 FR 5232, Jan. 19, 1993]

§493.1253 Condition: Hematology.

To meet the quality control requirements for hematology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) Cell counts performed manually using a hemocytometer must be tested in duplicate. One control is required for each eight hours of operation.

(b) For non-manual hematology testing systems, excluding coagulation, the laboratory must include two levels of controls each eight hours of operation.

(c) For all non-manual coagulation testing systems, the laboratory must include two levels of control each eight hours of operation and each time a change in reagents occurs.

(d) For manual coagulation tests—

(1) Each individual performing tests must test two levels of controls before testing patient samples and each time a change in reagents occurs; and

(2) Patient and control specimens must be tested in duplicate.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5232, Jan. 19, 1993]

§493.1255 Condition: Pathology.

The laboratory must meet the applicable quality control requirements in §§493.1201 through 493.1221 and §§493.1257 through 493.1261 of this subpart for the subspecialties for which it is certified under the specialty of pathology. All quality control activities must be documented.

§493.1257 Condition: Cytology.

To meet the quality control requirements for cytology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and paragraphs (a) through (g) of this section.

(a) The laboratory must assure that—

(1) All gynecologic smears are stained using a Papanicolaou or modified Papanicolaou staining method;

(2) Effective measures are taken to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process;

(3) Nongynecologic specimens that have a high potential for cross-contamination are stained separately from other nongynecologic specimens, and the stains are filtered or changed following staining;

(4) Diagnostic interpretations are not reported on unsatisfactory smears; and

(5) All cytology slide preparations are evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

(b) The laboratory is responsible for ensuring that—

(1) Each individual engaged in the evaluation of cytology preparations by nonautomated microscopic technique examines no more than 100 slides (one patient per slide, gynecologic or nongynecologic, or both) in a 24 hour period, irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and is not to be employed as a performance target for each individual. Previously examined negative, reactive, reparative, atypical, premalignant or malignant gynecologic cases as defined in paragraph (c)(1) of this section, previously examined nongynecologic cytology preparations, and tissues patholoty slides examined by a technical supervisor qualified under §493.1449 (b) or (k) are not included in the 100 slide limit. (For this section, all references to technical supervisor refer to individuals qualified under §§493.1449 (b) and (k).);

(2) For purposes of workload calculations, each slide preparation (gynecologic and nongynecologic) made using automated, semi-automated, or other liquid-based slide preparatory techniques which result in cell dispersion over one-half or less of the total available slide area and which is examined by nonautomated microscopic technique counts as one-half slide.

(3) Records are maintained of the total number of slides examined by